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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,954	03/19/2004	Marise S. Gottlieb		8077

7590 10/05/2007

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,954	GOTTLIEB, MARISE S.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-18* is/are pending in the application.

4a) Of the above claim(s) *8-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on May 23, 2007.

Claims 1-4 and 6-18 are pending in the application.

Any rejection from the previous office action, which is not restated here, is withdrawn.

The species comprising administering "YG Product" for controlling chronic inflammation in an individual having "obesity associated with the Metabolic Syndrome" is examined below. The search was broadened and also encompasses "impaired glucose tolerance associated with the Metabolic Syndrome"

Claims 1-4 and 6-7 are presented for examination on the merits. Claims 8-18 are withdrawn as not drawn to the elected Group.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991).

Gottlieb teaches a method for controlling rheumatoid arthritis in an individual, comprising administering to said individual an effective dosage of a pharmaceutical composition of YG-Product (e.g., abstract, lines 6-14; page 25, lines 22-29; page 45, lines 1-6). Gottlieb also teaches administering YG-Product with a dermal patch to treat a diabetic, which reads upon an individual having Metabolic Syndrome (see, e.g., page 45, lines 6). Gottlieb does not teach that rheumatoid arthritis is a chronic inflammation disease nor does it teach using elevated levels of C-Reactive Protein, serum fibrinogen, platelet count or platelet activity as markers for chronic inflammation.

Persselin teaches that rheumatoid arthritis necessarily reads upon a chronic systemic inflammatory disease (page 73, column 1, lines 1-3) and that elevated C-reactive protein levels and platelet counts serve as indicators of disease activity (e.g., abstract, lines 20-23).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to a diabetic suffering rheumatoid arthritis using a dermal patch as taught by Gottlieb. The skilled artisan would have been motivated to do so because Gottlieb teaches that YG product may be used to treat rheumatoid arthritis and diabetes (page 25, lines 22-29, page 45, lines 1-6). There would have been a reasonable expectation of success, given that Gottlieb taught that dermal patch administration of YG-product (see, e.g., page 45) was faster, required less skill and was lees annoying to patients, plus it had a long lasting therapeutic effect, and because Gottlieb taught that YG-product had therapeutic effect over diabetes and over rheumatoid arthritis. Thus the invention as a whole was

clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991) in view of L'Italien et al. (US 6,136,784).

Gottlieb and Persselin are relied upon as above. Gottlieb and Perssellin do not teach treating an obese individual.

L'Italient et al teaches that diabetes type I is treated commonly with insulin therapy, which is known to cause weight gain as taught by L'Italien et al. (US 6,136,784) [column 6, lines 31-43] and also teaches that many type 2 diabetes patients are often obese (column 2, lines 15-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to an obese diabetic suffering rheumatoid arthritis. The skilled artisan would have been motivated to do so because Gottlieb teaches that YG product may be used to treat rheumatoid arthritis and diabetes (page 25, lines 22-29, page 45, lines 1-6) and because obesity is present as a side effect or precursor to diabetes as taught by L'Italien. There would have been a reasonable expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991) in view of Fletcher et al. (JCI, 1952) and in view of Harris (Diabetes Care, 1998).

Gottlieb and Persselin are relied upon as above. Gottlieb and Persselin do not teach the limitations of claim 6, e.g., impaired glucose tolerance or increased fibrinogen.

Harris et al. teach that impaired glucose tolerance is associated to diabetes (e.g., Figures 3; Tables 3-4; page 524, column 1)

Fletcher et al. teach that high levels of fibrinogen are present in rheumatoid arthritis (e.g., page 562, column 1, Results; page 570, column 1 summary).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb to treat rheumatoid arthritis with high levels of fibrinogen as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4 and page 524) in diabetic patients having impaired glucose tolerance as taught by Harris et al. (e.g., Figures 3; Tables 3-4; page 524, column 1). The skilled artisan would have been motivated to do so because high levels of fibrinogen had been found in rheumatoid arthritis as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4, page 524) and because impaired glucose tolerance was correlated with diabetes as taught by Harris et al. (e.g.,Figures 3; Tables 3-4; page 524, column 1). There would have been a reasonable expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb et al. (US 5,0113,546) and in view of Persselin (Clin Orthop Relat Res, 1991).

Gottlieb US '380 teaches a method for controlling rheumatoid arthritis and diabetes in an individual, comprising administering to said individual an effective dosage of a pharmaceutical composition of containing amplifier Beta (e.g., claims 1, 3-4, 8 and 14).

Gottlieb et al., US '546, teach that amplifier Beta includes Beta 1.11, which is corresponding to YG material (e.g., column 3, lines 38-68 and column 4, lines 1-68 and claims 1-3).

Persselin teaches that rheumatoid arthritis necessarily reads upon a chronic systemic inflammatory disease (page 73, column 1, lines 1-3) and that elevated C-reactive protein levels and platelet counts serve as indicators of disease activity (e.g., abstract, lines 20-23).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to a diabetic suffering rheumatoid arthritis as taught by Gottlieb 'US 380 (e.g., abstract, claims 1, 3-4, 8 and 14). The skilled artisan would have been motivated to do so because Gottlieb US '380 teaches amplifier beta (which reads upon YG product according to Gottlieb et al. US '546, e.g., column 3, lines 38-68; column 4, lines 1-68, and claims 1-3) may be used to treat rheumatoid arthritis and diabetes with amplifier Beta (claims 1, 3-4, 8 and 14). There would have been a reasonable expectation of

success, given that Gottlieb US '546 teaches that amplifier Beta encompasses YG-product (see, e.g., column 13, lines 33-37 and claims 1-3). Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb et al. (US 5,0113,546) in view of Persselin (Clin Orthop Relat Res, 1991) and in view of L'Italien et al. (US 6,136,784).

Gottlieb and Persselin are relied upon as above. Gottlieb and Perssellin do not teach treating an obese individual.

L'Italient et al teaches that diabetes type 1 is treated commonly with insulin therapy, which is known to cause weight gain as taught by L'Italien et al. (US 6,136,784) [column 6, lines 31-43] and also teaches that many type 2 diabetes patients are often obese (column 2, lines 15-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to an obese diabetic suffering rheumatoid arthritis. The skilled artisan would have been motivated to do so because Gottlieb teaches that YG product may be used to treat rheumatoid arthritis and diabetes (e.g., US '380, claims 1, 3-4, 8 and 14) and because obesity is present as a side effect or precursor to diabetes as taught by L'Italien. There would have been a reasonable expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product. Thus the

invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb et al. (US 5,0113,546) in view of Persselin (Clin Orthop Relat Res, 1991) in view of Fletcher et al. (JCI, 1952) and in view of Harris (Diabetes Care, 1998).

Gottlieb and Persselin are relied upon as above.

Gottlieb and Persselin do not teach the limitations of claim 6, e.g., impaired glucose tolerance or increased fibrinogen.

Harris et al. teach that impaired glucose tolerance is associated to diabetes (e.g., Figures 3; Tables 3-4; page 524, column 1)

Fletcher et al. teach that high levels of fibrinogen are present in rheumatoid arthritis (e.g., page 562, column 1, Results; page 570, column 1 summary).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb to treat rheumatoid arthritis with high levels of fibrinogen as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4 and page 524) in diabetic patients having impaired glucose tolerance as taught by Harris et al. (e.g.,Figures 3; Tables 3-4; page 524, column 1). The skilled artisan would have been motivated to do so because high levels of fibrinogen had been found in rheumatoid arthritis as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4, page 524) and because impaired glucose tolerance was correlated with diabetes as taught by Harris et al.

(e.g.,Figures 3; Tables 3-4; page 524, column 1). There would have been a reasonable expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product (e.g., US '380, claims 1, 3-4, 8 and 14). Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's Arguments

Applicant argues that the inventor of Gottlieb was the husband and professional colleague of the inventor of the present application, and that when Gottlieb mentions diabetes, he refers to Type I diabetes even if not expressly taught. Therefore the Examiner is taking the reference to didabetes out of proper context. Applicant also indicates that the reference to Persselin is also not proper because Persselin's paper does refer to rheumatoid arthritis as a chronic inflammatory disease, he appears to be dealing with this disease strictly from a clinical point of view. The cause of rheumatoid arthritis is an autoimmune reaction in which the joints are attacked by the patient's own immune system, resulting in damage to the joints. Such destruction subsequently results in chronic inflammation from rubbing of unprotected bone. Gottlieb, in his earlier patents discuses treatment of the autoimmune reaction, NOT the subsequent inflammation. That is claims 1-3 are directed to the control of chronic inflammation in an individual having Metabolic Syndrome. That is, Claims 1-3 of the present application are directed to the control of chronic inflammation associated with Metabolic syndrome. The present invention teaches that since chronic antigenic stimulation resulting from

immune dysfunction leads to the inflammatory condition which is characteristic of the Metabolic Syndrome, then correction of immune dysfunction can reduce the symptoms and characteristics of the Metabolic Syndrome, then correction of immune dysfunction can reduce the symptoms and characteristics of the Metabolic Syndrome, and thus the factors leading to Metabolic Syndrome related diabetes mellitus and coronary heart disease. Persselin does not disclose that the cause of rheumatoid arthritis is associated with Metabolic Syndrome. As stated above, the autoimmune reaction of Rheumatoid Arthritis, results in a decrease of joint cartilage and inflammation secondary to the joint bones rubbing against each other, without protection normally provided by the cartilage. What is important for the examiner to understand that inflammation may be caused by many things.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive because the claims are drawn to a method for controlling chronic inflammation in an individual having Metabolic Syndrome, comprising administering to said individual an effective dosage of YG-product. Please note that the origin of the chronic inflammation is not specified, thus, the claims read upon treating any type of chronic inflammation in an individual having Metabolic Syndrome. Also, please note that L'Italient et al teaches that diabetes type I is treated commonly with insulin therapy, which is known to cause weight gain as taught by L'Italien et al. (US 6,136,784) [column 6, lines 31-43] and also teaches that many type 2 diabetes patients are often obese (column 2, lines 15-17).

It has been held that under KSR that "obvious to try" may be an appropriate test under 103 The Supreme Court stated in KSR:

> When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007).

The "problem" facing those in the art was the treatment of chronic inflammation in an individual having Metabolic Syndrome (such as having diabetes Type II), and there were a limited number of methodologies available to do so, such as treating chronic inflammation generated by rheumatoid arthritis with YG-Product as taught by Gottlieb (EP 0230 052 A2). Gottlieb does not teach the application of YG-Product is limited to any population, and therefore, an obese person with diabetes type II and rheumatoid arthritis would still be expected to have a decrease in chronic inflammation when treated with YG-product. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. In the instant case Gottlieb teaches YG-product can be used in correcting immune deficiency imbalances such as that seen in rheumatoid arthritis (e.g., abstract), which read upon "treating chronic inflammation" as taught by Persselin above. Thus, treating chronic inflammation (resulting from rheumatoid arthritis) in a diabetes type II obese individual or in any other type of individuals is a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.

In addition, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness.

See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Patt. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2s at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6-7 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8 and 13 of U.S. Patent No. 4,710,380 in view of U.S. Patent No. 5,013,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant

application and US '380 are both drawn to a method for controlling chronic inflammation (e.g., rheumatoid arthritis, claim 4) in an individual having Metabolic Syndrome [such as a diabetic] (claim 8) comprising: administering to said individual an effective dosage of amplifier Beta, which reads upon YG-product as taught by US 5,013,546 (see, e.g., column 13, lines 33-37 and claims 1-3). Further, the instantly claimed method encompasses and/or is encompassed by the claimed method of US '380.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MMCG 09/07

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